Atherosclerosis Risk in Communities Study Protocol

Manual 13a

Magnetic Resonance Imaging Protocol

Visit 3

Version 1.0

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FOREWORD

This manual, entitled Magnetic Resonance Imaging Protocol, is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 15. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

ARIC Study Protocols and Manuals of Operation

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5	Electrocardiography
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MANUAL 13A

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1.0 MAGNETIC RESONANCE IMAGING - VISIT 3

1.1 Introduction

The Atherosclerosis Risk in Communities (ARIC) Study is an epidemiological examination of the major factors contributing to the occurrence and trend of cardiovascular disease in middle-aged (age 35-74) adults in the United States. The study has two main objectives: to investigate factors associated with both atherosclerosis and incidence of clinical cardiovascular disease, and to measure coronary heart disease (CHD) occurrence and trends and relate them to community levels of risk factors, medical care and atherosclerosis.

At inception, the ARIC cohort consisted of approximately 4,000 persons (roughly equal numbers of men and women) aged 45-64 in each of four US communities: Forsyth County, North Carolina (biracial); Jackson, Mississippi (all black); suburbs of Minneapolis, Minnesota, and Washington County, Maryland. Examinations are conducted every three years on cohort participants. It is estimated that about 14,500 persons will be seen at the third examination visit that begins in March, 1993 and extends for three years.

Selected participants at two of the ARIC community Field Centers (Forsyth County and Jackson) receive cerebral magnetic resonance imaging (MRI) examinations. The pilot study, consisting of 10 volunteers in each Field Center, was conducted during February, 1993. The main study consists of approximately 2,000 MRI studies to be completed over a two-year period beginning in March, 1993.

The role of the ARIC cerebral MRI Field Centers is to perform approximately 2,000 MRI exams in ARIC. The MRI Reading Center assisted in protocol development for cerebral MRI and will perform interpretations of these images in a standardized and reproducible manner.

1.2 Rationale and Goals

The goal of the ARIC cerebral MRI component is to evaluate cerebral changes detected by MRI in a representative biracial population aged 56-70 and to evaluate the relationship of these images to clinical stroke, coronary heart disease, cardiovascular risk factors, retinal microvascular changes, extracranial carotid atherosclerosis and changes in cognitive function.

The MRI data are expected to supplement current ARIC clinical descriptors of cerebrovascular disease (CBVD) by increasing the sensitivity of detecting CBVD, by including subclinical disease, and by distinguishing small-vessel from large-vessel disease. These data will form the basis for testing a number of hypotheses about the relationship between current ARIC clinical descriptors of CBVD and the criteria of CBVD as identified by MRI. A representative sample of the ARIC clinical descriptors and MRI criteria of CBVD are listed below:

ARIC Clinical Descriptors of CBVD	MRI Variables of CBVD
Stroke (CVA)	Type of Stroke Ischemic Major vessel Small vessel Hemorrhagic Number, Size
Transient Ischemic Attack(TIA)	
Approximate Location	Location Frontal Parietal Occipital Temporal Cerebellum Brain Stem
Dementia	Subcortical White Matter Disease (SWMD)
	Brain atrophy (reflected by): Sulcal size Ventricle size

The ability to perform correlations between current ARIC measures of CBVD and MRI measures of CBVD is key to testing several hypotheses for the relationship between CBVD risk factors and clinical/subclinical CBVD, including cognitive decline and dementia:

(1) Risk factor profiles in small vessel disease (SVD) (such as lacunar CVA or possibly SWMD) and hemorrhagic CVA differ from those in large vessel disease (LVD) (such as myocardial infarction (MI), extracranial carotid atherosclerosis, or large vessel atherothrombotic stroke).

(2) The prevalence of SVD relative to LVD is greater in blacks and women than in whites and men, respectively.

(3) Early hypertensive changes noted in retinal arterioles are associated with or predict CBVD, especially SVD, independently of blood pressure and other risk factors.

(4) Small incidental cerebral lesions (sometimes referred to as subcortical white matter "disease") seen on MRI in healthy people with increasing frequency in advancing age are predicted by blood pressure and are associated with early hypertensive changes in retinal arterioles and decline in cognitive function.

(5) MRI evidence of CBVD predicts future CBVD events and cognitive decline.

1.3 MRI Equipment

The following are the Field Center MR Instruments used in the ARIC MR study.

1. Bowman Gray - GE Signa 1.5 T or Picker 1.5 T
2. Jackson - GE Signa 1.5 T

Any changes in imaging equipment at the Field Centers requires prior approval from both the MRI Reading Center and the ARIC Steering Committee.

1.4 MRI Field Center Personnel

1.4.1 Field Center ARIC Neuroradiologist

At each of the two Field Centers there is a designated neuroradiologist. This person is responsible for the performance of MRIs at his/her ARIC Field Center (FC). The ARIC neuroradiologist monitors the study closely to insure adherence to MRI imaging protocol, including proper handling of alerts, and maintenance of appropriate quality control of the ARIC studies and MRI imaging equipment. The ARIC MRI neuroradiologist also supervises the ARIC MRI technologist and provides all training needed to perform the imaging protocol. He/She is also responsible for the interpretation of alert conditions detected at the ARIC MRI center, and for processing them as specified in this protocol.

1.4.2 Qualifications for Field Center MRI Technologists

Field Center MRI technologists must have appropriate knowledge of cross-sectional anatomy, physiology, and pathologic processes with emphasis on neurologic imaging. The preferred level of education is completion of a two year AMA approved program for diagnostic imaging and a minimum of 3 to 6 months MRI experience. The technologist must have a basic knowledge of MRI and/or knowledge of computer software applications, multi-format cameras, processors and video recording devices.

In addition to the above education and MRI experience, the ARIC MRI technologist must have a complete understanding of the MRI ARIC Imaging Protocol. This requires training to identify the anatomical location of the AC/PC Line and implementation of the ARIC MRI pulse sequences. The MRI technologist must also be trained and competent to recognize conditions identified as notification alerts in this manual.

1.5 Selection of Study Participants

Members of the ARIC cohort at Forsyth County and Jackson who are 56 years of age or older at the time of their Visit 3 examination are eligible for the cerebral magnetic resonance imaging (MRI) examination. Field center personnel explain the study procedure and its purpose (Appendix 1.1) to age-eligible individuals, and screen them for reasons for exclusion from an MRI examination using the standard MRI Screening Form (MSC: Appendix 1.2). The following are reasons for exclusion identified on the MRI Screening Form: having had surgery on an aneurysm in the brain; having metal fragments in the eyes, brain, or spinal cord; having a valvular prosthesis, a cardiac pacemaker, cochlear implant, spinal cord stimulator, or other internal electrical device; and pregnancy. If the latter cannot be ruled out, the staff person schedules a call at a later date.

If the participant passes all exclusion criteria the staff person administers the Informed Consent Form (Appendix 1.3), with a full explanation of the procedure, its potential risks, and benefits. Scheduling the MRI examination takes place at this time, either by telephone or during the participant's regular cohort re-examination visit. Before the MRI examination is performed, a staff person of the MRI Center explains the procedure again, as described below, and another form is signed by the participant to indicate that he/she has been fully informed and has agreed to the examination.

1.6 Participant Preparation and Instructions

The MRI technologist explains the study procedure to the ARIC participant and answers any questions. The participant is instructed to remove any metallic objects, including jewelry, dentures, hearing aids, hairpins, etc. and to secure all items in the patient's locker. The technologist explains to the participant that the exam will take approximately 30 minutes. The participant is told that there are microphones in the MRI machine to communicate with the technologist and that the exam may be stopped at any time. The participant is also told that movement, and/or speaking during the exam will compromise the quality of the images, and is asked to refrain from such activity during the scan. Prior to escorting the participant into the scan room, the technologist verifies that all equipment necessary for the exam is ready. The technologist accompanies the participant into the scanning room and offers assistance in getting on to the scanning table and the participant is told that the table will move into the scanner. After the participant is comfortably positioned on the table, the technologist explains that positioning aids will be placed along the sides of the head to help him/her to hold still, and a helmet-like apparatus placed about their head. Knee pillows and ear plugs are also offered. The longitudinal localizing light is used to align the mid-sagittal plane. The participant is asked to close his/her eyes, and the transverse light is aligned along the lids of the eyes. The technologist reminds the participant to refrain from movement during the exam, adjusts the head coil, advances the participant into the magnet and enters the necessary information into the system.

1.7 Scanning of the ARIC MRI Participant

For purposes of archiving and retrieval, it is required that the ARIC identification number be placed in the ID field, and that the name field be filled with the letters ARC and the ID number, with no space between them. The examples shown below need to be followed exactly:

ID: F123456 NAME: ARCF123456

ID: J123456 NAME: ARCJ123456

1.7.1 MRI Scanning Protocol

The MRI scanning protocol is to be followed exactly as described in this manual. If the Field Center needs to revise the protocol due to modifications in equipment or software, the revised protocol must be approved by the MRI Reading Center Principal Investigator prior to scanning an ARIC participant.

1.7.2 MRI Imaging Protocol

Scanning pulse sequences should be performed in the following order:

Series 1 - Sagittal T1-weighted localizing scan used to identify AC/PC line, TR 500 (400-600), TE 20 (<35), 5 mm, 0 gap, 128 x 256 matrix, 1 nex, images centered to midline.

Series 2 - Angled (Parallel to AC/PC line) axial spin density SD/T2-weighted scans, TR 3000 (>2500), TE 30,100 (<35/>75), flow comp, 5 mm, 0 gap, interleaved 256 x 192 matrix, 1/2 nex, (1 nex on less than 1T scanners), images obtained from vertex to skull base.

Series 3 - Angled (Parallel to AC/PC line) axial T1- weighted scans TR 500 (400-600), TE 20 (<35), 5 mm, 0 gap, 256 x 192 matrix, 1 nex (2 nex on less than 1T scanners), cover vertex to skull base. The slice positions on series 2 and 3 should match.

Upon reviewing scans, if extensive artifacts are evident on images, the sequence is repeated once, if possible. Series # 2 must be completed for interpretation purposes. If for some reason series 2 is not completed, the study should not be sent to the MRI Reading Center. Although it is up to the individual Field Center whether to perform additional sequences, only information collected according to the ARIC protocol can be put on the magnetic tape sent to the MRI Reading Center. It is also up to the individual Field Center whether to "hard copy" these studies on film. The MRI Reading Center only requires the study on magnetic tape or disk. To prevent the loss of a tape or disk during shipment, it is highly desirable that each study be stored at the local MRI facility with regular clinical studies.

1.7.3 Localization of AC/PC Line

1.7.3.1 Anterior Commissure

The Anterior Commissure is a two to three mm vertically ovoid white matter structure located along the anterior wall of the third ventricle at approximately one third of the distance from the bottom of the rostrum of the corpus callosum to the top of the optic chiasm. It has the same signal intensity as the corpus callosum.

1.7.3.2 Posterior Commissure

The Posterior Commissure is the small focus of tissue located immediately posterior and superior to the junction of the cerebral aqueduct and the third ventricle.

1.7.3.3 AC/PC Line

The Anterior Commissure/Posterior Commissure line passes through the superior edge of the Anterior Commissure and the inferior edge of the Posterior Commissure.

Figure 1.

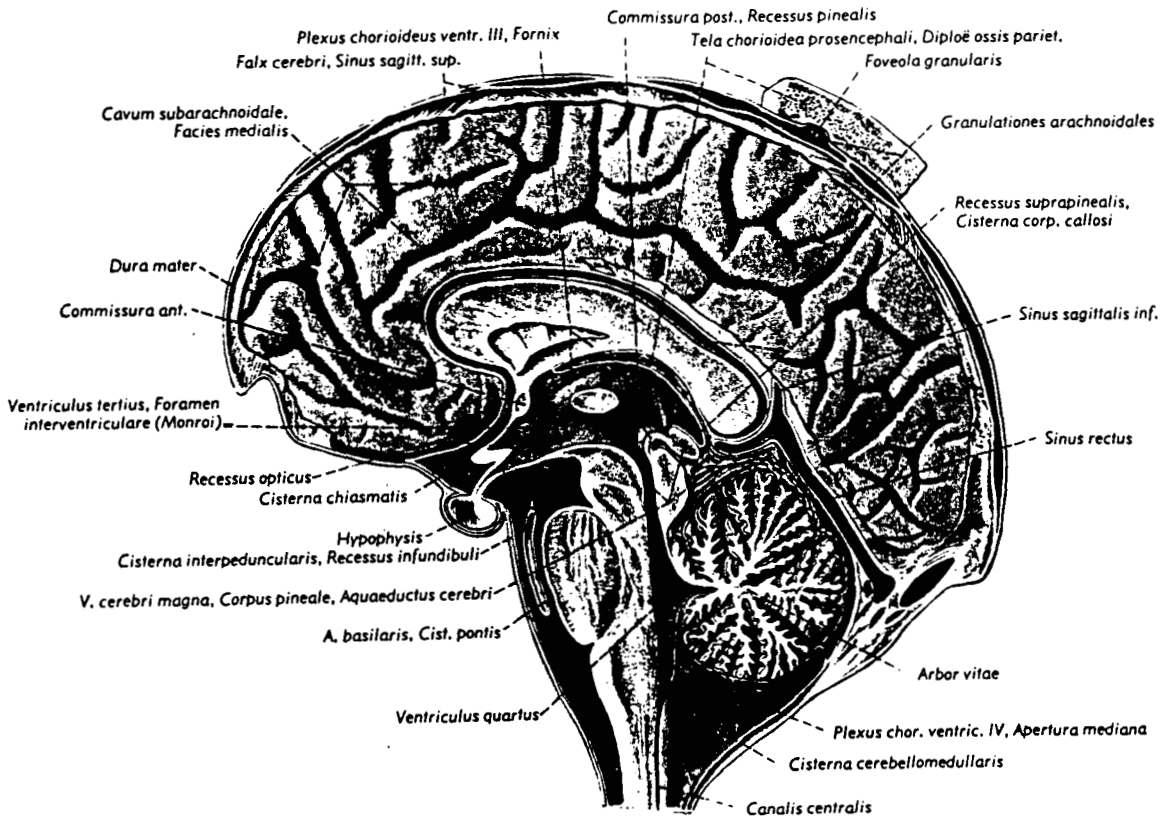
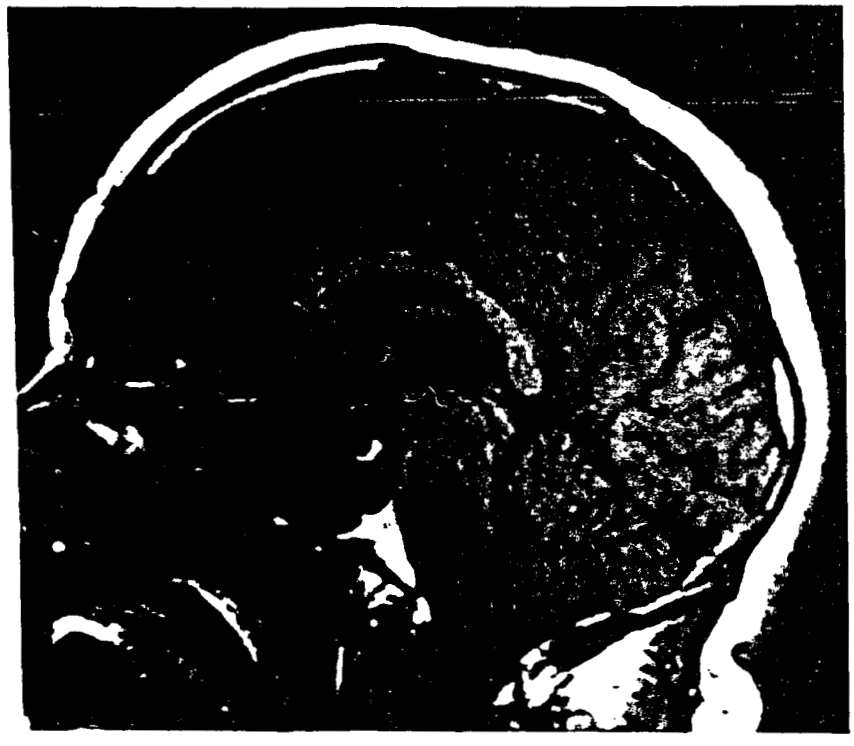


Figure 2.



1.7.4 Archiving Instructions

1. Archive on magnetic tape/disk series 1.
2. Archive Series 2 from vertex to base.
3. Archive Series 3 from vertex to base
4. If additional sequences are performed at a Field Center, these must not be included on the magnetic tape/disk for interpretation.

1.8 After Completion of the MRI Study

After each MRI study is completed, the MRI technologist fills the MRI Procedure Form (Appendix 1.4). This form is also filled for every examination that is scheduled but not attempted, or attempted but not completed according to the ARIC protocol. The Procedure Form also serves to record the scanning pulse sequence, the orientation of the oblique axial scan, and whether any emergent alert conditions were noted. If the latter is the case, the condition is recorded on the form, as is the name of the person who was notified, and the alert notification date.

The ARIC Field Center staff retrieves the data tapes (or disks) from the MRI Center once per week, and follows standard procedures for shipping them to the MRI Reading Center. The MRI Procedure Form (completed by the MRI technologist) is reviewed by the ARIC staff to verify that the form is complete and the identifying information correct. The Field Center staff completes the MRI Weekly Log Sheet (Appendix 1.5). The participants' initials, ID number label, and dates of scan are transferred on this log sheet, which is sent with the magnetic tapes (disks) to the MRI Reading Center. Each magnetic tape is labelled with the ID number and initials of the participant contained on that tape. The MRI Completion Form (Appendix 1.6) corresponding to each participant study included in the shipment is also added to the mailer.

1.9 Management of Magnetic Tapes

Tapes containing studies performed on Picker scanners are labelled as Picker tapes to let the MRI Reading Center know which scanner was used for each study.

On an assigned day each week, the ARIC staff prepares the tapes for mailing. This includes ascertaining that all tapes are labelled completely, packing them securely, checking the contents of the shipping container against that week's log sheet, copying the log sheet and MRI Completion Forms, stapling the Completion Forms for that week to the original log sheet, and mailing the package to the MRI Reading Center on schedule. A copy of each log sheet is kept at the Field Center. Once the magnetic tapes are sent to the MRI Reading Center they are retained there permanently.

Each tape can contain approximately 3 MRI scans. If on the assigned shipping day a tape has only 1 or 2 scans on it, it is included with that week's shipment. Magnetic tapes/disks are mailed via Federal Express or equivalent carrier (48 hour delivery).

Magnetic Tapes are mailed to:

Linda Wilkins, R.T.
Johns Hopkins Hospital
Dept. of Neuroradiology
Nelson B-100
600 N. Wolfe Street
Baltimore, Md. 21205
(410) 955-8216

1.10 Procedure for Optical Disks

The procedure for handling optical disks differs slightly from the above procedure for magnetic tapes.

Field Centers using optical disks allocate approximately 3-4 disks (or as many as needed to hold approximately 1,000 MR studies) to the ARIC study. These optical disks become the property of the ARIC MRI study and should only contain the ARIC MRI protocol studies on them. At the end of the study or when an optical disk becomes full (whichever occurs first), the optical disk is sent to the ARIC MRI Reading Center for permanent storage.

At the beginning of the study the ARIC Field Center and the MRI Reading Center establish a rotation exchange process for these optical disks. Optical disks are identified with a permanent label, which specifies the disk number and side (a or b). For example:

ARIC MRI STUDY
DISK #1 SIDE A

Each ARIC MRI Center can place approximately 20-25 MR participants studies (approximately two weeks of participant MR exams) on such a disk. The MRI Optical Disk Log (Appendix 1.7) is completed with all pertinent information provided. This disk log is copied prior to mailing by the study coordinator. Additions to the log are made each time more participant studies are added to disk #1.

At the completion of the 20-25 studies this disk and the original log which accompanies it are sent to the MRI Reading Center via Federal Express or equivalent carrier (48 hour delivery) to:

Linda Wilkins, R.T.
Johns Hopkins Hospital
Division of Neuroradiology
Nelson B-100
600 N. Wolfe Street
Baltimore, MD 21205
(410) 955-8216

When disk #1 has been sent to the MRI Reading Center, the Field Center starts the next batch of participant studies on disk #2, and a new disk log for disk #2. This log is then sent following the same procedure as used for disk #1.

Upon receipt of the disks the MRI Reading Center data manager archives these studies, logs the studies received by shipment date and returns the disk to the Field Center so that more ARIC MRI studies can be added to this disk. Studies are never to be deleted from these optical disks. The MRI Reading Center retains a separate log for each disk in the rotation. The rotation exchange of optical disks may require 3-4 disks at any one time, to eliminate any delay due to mailing or scheduling.

This system results in 2 separate logs - one at the MRI Reading Center and one at the ARIC Field Center. Each disk has a separate log associated with it, at each location.

1.11 Assessing the Acceptability of the MRI Examination

During the initial six months of the MRI study, each Field Center conducts a survey to monitor the acceptability of the MRI examination. The Study Coordinator and the Field Center PI monitor the survey results to ascertain any concerns on the part of the study participants. At the conclusion of 24 interviews at each Field Center, the copies of the completed forms are sent to the Chair of the Cohort Committee for summarization and distribution.

2.0 QUALITY CONTROL

2.1 Image Quality Control

Prior to an ARIC participant leaving the Field Center MRI Unit, the MRI technologist reviews the scan. This includes a check to see that the protocol is complete and the scans are technically satisfactory. If a series needs to be repeated, it is done at this time, to avoid bringing the participant back.

2.2 Equipment

A formal evaluation of the physical performance parameters of each machine will be conducted at regular intervals by the Field Center using standard manufacturer-recommended evaluation methods. Each Field Center has at its disposal MR calibration phantoms. These phantom images provide evaluation of field homogeneity, noise characteristics, spatial, and contrast resolution.

At the start of the study and once a year thereafter, the ARIC Field Centers send a phantom quality control scan to the MRI Reading Center. If this phantom scan is sent on magnetic tape, a separate tape is used, labeled as a phantom. If sent on optical disc, it is included with the regular ARIC participant studies but identified on the disc as a phantom. The phantom scan is mailed to:

Linda Wilkins, R.T.
Johns Hopkins Hospital
Division of Neuroradiology
Nelson B-100
600 N. Wolfe Street
Baltimore, MD 21205
(410) 955-8216

2.3 Field Center Performance Reports

At the end of the pilot study, the MRI Reading Center makes a site visit to each of the two Field Centers. The purpose of the site visit is to meet all ARIC personnel and to observe the scanning of an ARIC participant or volunteer. Questions related to the MRI study are addressed at that time.

The MRI Reading Center maintains an ongoing review of each Field Center to monitor the number of studies acceptable for interpretation; the number of studies rejected for protocol non-compliance; and the number of studies found to be technically suboptimal. If a Field Center is found to have more than 10% of studies unacceptable for interpretation, the MRI Reading Center requests a report from the Field Center documenting the reasons for the deficiencies and the proposed corrective actions. Two weeks after receipt of the Field Center report the MRI Reading Center verifies that corrective measures have been taken. Copies of these reports are provided by the MRI Reading Center to the ARIC Quality Control Committee.

3.0 PARTICIPANT SAFETY: ALERT NOTIFICATION

3.1 Background and Rationale

Study participants with certain MR scan abnormalities may require further medical attention. ARIC does not assume responsibility for diagnosis and management of its participants, but has assumed an obligation to refer such cases to their local source of medical care. The referral system is based on the urgency of the MR abnormality. An "alert" is defined as an immediate or urgent referral.

Result categories:

A. No participant referral indicated
   1. no clinically significant findings

B. Participant referral optional.
   1. old infarcts, white matter ischemic changes, atrophy, other chronic abnormalities

C. Urgent referral (alert)
   1. tumor without significant mass effect, AVM, aneurysm, obstructive hydrocephalus
   2. Cavernous angioma, venous angioma
   3. Arterial occlusion (or slow flow)

D. Immediate referral (alert)
   1. acute subdural or epidural hematoma, subarachnoid hemorrhage, acute intraparenchymal hematoma, acute infarct, subacute infarct, obstructive hydrocephalus (some cases), cerebral venous thrombosis, abscess and suspected tumor with significant mass effect

Conditions not listed here which require referral in the opinion of an MR technician are triaged and reported accordingly, per the judgement of the Field Center or Reading Center neuroradiologist. Doubtful cases are triaged to the more severe category.

3.2 Local MR Center Alert Management Procedures

The MR technologist at the local MR Center reviews each study for the presence of any condition identified by the ARIC protocol as an emergent alert. If such a condition is found, the neuroradiologist (referred to below as the MR Center physician) is notified, and this occurrence recorded on the MRI Procedure Form. After review of the potential alert by the MRI Center neuroradiologist, a brief report is prepared and the Field Center physician is notified. Each field center has identified a physician (and back-up) for this purpose. Key information describing this process is recorded on the MRI Procedure Form, such as a specification of the alert condition, the name of the Field Center person notified, and the date of this notification. A summary overview of this process is shown below.

Type of Referral	ACTION: Local MRI Center	ACTION: Field Center
None	None	Send report of the study results to participant and his/her physician
Urgent	The MRI Center physician prepares a report, and contacts the Field Center physician within 24 hours.	The Field Center physician contacts the participant and his/her physician.
Immediate	Same as Urgent Referral	Same as in Urgent Referral

3.3 Reading Center Alert Management Procedures

At the MRI Reading Center each participant's alert status is recorded in the MR results data file at the time of image interpretation. The alert status codes are shown below:

1 = No referral
2 = Routine referral (ARIC coordinating center option).
3 = Urgent referral required.
4 = Immediate referral required.

A value of 2 (routine referral) is entered automatically by the MRI Reading Center software. Readers then change this field to either 1, 3, or 4, as appropriate.

3.4 Communication with the Coordinating Center and Field Center(s)

1. The MR Reading Center sends the participants' MR results data file to the Coordinating Center by electronic mail or by shipping a diskette.

2. The portion of the MR results data file containing participant alert status and results to be reported to the participant is sent to the respective Field Center by electronic mail or disk.

When a condition identified by the ARIC protocol as an emergent alert is noted at the Reading Center, the alert status is recorded on the participant's result file, as described above. If the alert has previously been identified at the local MRI Center, as indicated on the MRI Procedure Form which accompanies each data shipment from the Field Center, no action is taken by the MRI Reading Center. If the MRI Procedure Form does not identify an alert, or refers to an alert condition different from that detected at the MRI Reading Center, the actions summarized below take place.

Type of Referral	ACTION: Local MRI Center	ACTION: Field Center
None	None	Send report of study results to participant and his/her physician
Urgent	The Reading Center physician prepares a brief report, which is included in the participant file	
	The Reading Center sends the MRI results data file (including alert status and clinical report) to the Field Center by electronic mail or fax.	The Field Center physician contacts the participant and his/her physician
	The Reading Center sends copy of the MR scan film to the Field Center by overnight delivery.	
Immediate	Same as Urgent Referral, and in addition:	Same as in Urgent Referral
	The Reading Center physician calls the Field Center contact by phone at the time of image interpretation.	

3.5 Report of Study Results to the Participant and His/Her Physician

When Field Center physicians communicate an emergent alert to the study participant and his/her physician, contact is made first by phone, followed by a letter. A copy of the report from the neurologist/neuroradiologist is enclosed with this letter. In the absence of alert conditions, the Field Center prepares a (routine) report to communicate the study results to the participant by mail. Overall, three types of reports serve this purpose: a) normal results; b) minor abnormal findings, no referral indicated; and c) referral for abnormal results.

Emergent reports originate from the process described above. Study results identified as notifiable on a routine basis, include (old) hematomas and their size, and (old) infarcts and their size. The data contained in these reports are extracted from the participant result file at the MRI Reading Center, and

sent to the Field Center for inclusion in the report to the participant and their physician.

The type of report distributed by the ARIC field centers is summarized below, as letters addressed to the study participant and the equivalent letters to his/her physician. A letter is also provided for the -- unusual -- occurrence of participants who do not identify a provider of medical care.

COVER LETTERS FOR RESULTS REPORTING TO PARTICIPANTS AND PHYSICIANS

RECIPIENT	TYPE OF RESULTS
Physician	a) Normal results b) Minor abnormal findings, no referral indicated c) Referral for abnormal results d) Abnormal results participant not informed
Participant	a) Normal results b) Minor abnormal findings, no referral indicated c) Referral for abnormal results d) Normal, or abnormal results, no MD designated

Prototypes of these letters can be found in Appendix 2.0.

APPENDIX 1.0 MRI FORMS

Appendix 1.1 Instructions for an MRI Scan

WHAT AN MRI SCAN IS:

THIS EXAMINATION, CALLED AN MRI (MAGNETIC RESONANCE IMAGING) SCAN, USES MAGNETIC AND LOW ENERGY RADIOWAVES TO PRODUCE A SERIES OF PICTURES OF YOUR HEAD. IT DOES NOT USE ANY X-RAYS, RADIOACTIVE MATERIALS OR ANY FORM OF IONIZING RADIATION. IT, TO THE BEST OF OUR KNOWLEDGE, PRODUCES NO HARMFUL SIDE EFFECTS OR UNPLEASANT SENSATIONS. IT WILL BE ADMINISTERED BY A TECHNOLOGIST TRAINED IN ITS USE.

PREPARATION:

NO PREPARATION IS NECESSARY TO PERFORM AN MRI SCAN. THE EXAM IS NOT AFFECTED BY ANYTHING YOU MAY HAVE EATEN, DRUNK OR ANY MEDICATION YOU MAY HAVE TAKEN.

PRECAUTIONS:

THE PRESENCE OF ANY METALLIC OBJECTS EITHER ON YOUR PERSON, CLOTHING OR IN YOUR BODY MAY INTERFERE WITH THE SCAN. BEFORE THE SCAN IS DONE, THE TECHNOLOGIST WILL ASK YOU TO REMOVE ALL JEWELRY, WATCHES, HAIRPINS, (GLASSES, WALLETS AND THE LIKE, AND CHANGE INTO HOSPITAL GOWNS. IMPORTANT: IF YOU HAVE UNDERGONE SURGERY ON YOUR HEAD OR BRAIN FOR WHICH INTERNAL METAL CLIPS MAY HAVE BEEN LEFT IN PLACE, PLEASE TELL THE TECHNOLOGIST ABOUT THIS BEFORE GETTING ON THE SCANNING TABLE. ALSO, PLEASE TELL THE TECHNOLOGIST IF YOU HAVE A CARDIAC PACEMAKER OR ARTIFICIAL METALLIC JOINT.

WHAT HAPPENS DURING AN MRI SCAN:

AFTER YOU HAVE CHANGED INTO HOSPITAL GOWNS AND REMOVED ALL METAL OBJECTS, THE TECHNOLOGIST WILL POSITION YOU ON A SPECIAL TABLE. YOUR HEAD WILL BE PLACED IN A PADDED PLASTIC CRADLE OR ON A PILLOW, AND THE TABLE WILL THEN SLIDE INTO THE SCANNER. IT WILL SEEM AS THOUGH YOU ARE BEING ROLLED INTO A LONG TUNNEL.

OUTSIDE THE SCANNER TUNNEL SURROUNDING YOUR HEAD AND BODY, THERE IS A LARGE MAGNET WITH A RADIO TRANSMITTER AND RECEIVER. INFORMATION FROM THESE INSTRUMENTS IS ACCUMULATED AND FED INTO A COMPUTER. THE COMPUTER THEN PRODUCES A SERIES OF PICTURES OF YOUR HEAD.

WHILE THE MACHINE IS TAKING YOUR PICTURES, YOU WILL HEAR REPEATING, LOUD THUMPING NOISES COMING FROM THE WALLS OF THE SCANNER. THEREFORE EARPLUGS WILL BE PROVIDED. ANY MOVEMENT, ESPECIALLY OF YOUR HEAD OR BACK (EVEN MOVING YOUR JAW TO TALK) DURING THIS TIME WILL SERIOUSLY BLUR THE PICTURES. DURING THE SCANNING, YOU SHOULD BREATHE QUIETLY AND NORMALLY BUT OTHERWISE REFRAIN FROM ANY MOVEMENT, COUGHING OR WIGGLING. WHEN THE THUMPING NOISE STOPS, THE PICTURES WILL BE PROCESSING AND YOU MAY RELAX FOR A FEW MINUTES, BUT YOU MUST REFRAIN FROM CHANGING YOUR POSITION OR MOVING ABOUT. THE ENTIRE EXAM ORDINARILY TAKES APPROXIMATELY 25 MINUTES.

Appendix 1.2 MRI Screening Form

ARIC MRI SCREENING FORM

Atherosclerosis Risk in Communities

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: M S C VERSION: A 03-09-93

LAST NAME: | | | | | | | | | | | | | INITIALS: | |

INSTRUCTIONS: This form should be completed during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

MRI SCREENING FORM (MSCA screen 1 of 4)

A. EXCLUSION

1. Have you ever had an MRI scan? ..... Yes Y
   No N

2. Have you ever had surgery on an aneurysm in your brain? ..... Yes Y
   No N
   Unknown U
   → Exclude, Go to Item 7.

3. Do you have metal fragments in your eyes, brain, or spinal cord? ..... Yes Y
   No N
   → Exclude, Go to Item 7.

4. Do you have a cardiac pacemaker or a heart valve prosthesis? Yes Y
   No N
   → Exclude, Go to Item 7.

5. Do you have any internal electrical devices, such as a cochlear implant or spinal cord stimulator? ..... Yes Y
   No N
   → Exclude, Go to Item 7.

6. [For females only] Could you be pregnant? ..... Yes Y
   No N
   Don't Know D
   → Exclude.

7. Does participant pass all MRI exclusion criteria? ..... Yes Y
   No N
   → Go to Item 16, Screen 4.

MRI SCREENING FORM (MSCA screen 2 of 4)

B. INTERVIEW

8.a. Have you ever had an injury that resulted in loss of consciousness (knocked out)? Yes Y

No N

Don't Know D

Go to Item 9a.

b. How many times? .....

9.a. Have you ever been in a coma? ... Yes Y

No N

Don't Know D

Go to Item 10.

b. What was the cause?

10. Have you ever been told you have cerebral palsy? ..... Yes Y

No N

Don't Know D

11. Have you ever been told you have a brain tumor? ..... Yes Y

No N

Don't Know D

12.a. Have you ever had an operation on your brain? ..... Yes Y

No N

Don't Know D

Go to Item 13, Screen 3.

b. What for?

MRI SCREENING FORM (MSCA screen 3 of 4)

13.a. Have you ever had a seizure or convulsion? ..... Yes Y

No N

Don't Know D

Go to Item 14.

b. Was this only as a child? Yes Y

No N

Don't Know D

Go to Item 14.

c. Did this occur within the last 5 years? ..... Yes Y

No N

Don't Know D

14. Do you have loss of memory other than for people's names? Yes Y

No N

Don't Know D

C. MRI APPOINTMENT INFORMATION

Read description of MRI procedure and invite participation.

15.a. Does participant agree to MRI? Yes Y

No N

Go to Item 16, Screen 4.

MRI SCREENING FORM (MSCA screen 4 of 4)

15.b. Would you please tell me why you don't want the MRI examination?

Go to Item 16.

- No time/interest N
- Claustrophobia C
- Previous MRI P
- Illness I
- Other O

c. If other, specify:

D. ADMINISTRATIVE INFORMATION

16. Date of data collection: ..... [ ][ ]/[ ][ ]/[ ][ ]
month day year

17. Method of data collection: ..... Computer C
Paper form P

18. Code number of person completing this form: ..... [ ][ ][ ]

Appendix 1.3 Informed Consent Form

ARIC PARTICIPANT LABEL

CONSENT FOR MAGNETIC RESONANCE IMAGING

Cerebral Magnetic Resonance Imaging for Stroke Risk Factors in the Atherosclerosis Risk in Communities (ARIC) Study

I have been invited to participate in a research study on the relationship between risk factors for stroke and the results of a type of brain scan known as magnetic resonance imaging (MRI). About 2000 men and women who are participating in the Atherosclerosis Risk in Communities (ARIC) study will have this procedure.

I understand that the MRI exam involves lying on a table inside of a large scanning device that will take pictures of my head using magnetic fields. The MRI device does not use ionizing radiation (such as x-rays), and is not known to have any significant risks. No blood will be drawn and no dye will be injected into my veins for this procedure. There is no physical pain. The study will require that I remain still for about 20 minutes so that the pictures can be made. Because the MRI machine is noisy, I understand that I must wear ear plugs or earphones. These will reduce any discomfort and any risk to my hearing. Some people may experience psychological discomfort in the scanner if they are uncomfortable in tight places (claustrophobia).

I am not pregnant; have not had prior surgery for an aneurysm (bulging of a large blood vessel due to a weakness of its wall) in my body or head; do not have metal fragments in my eyes, brain or spinal cord; do not have a cardiac pacemaker or a heart valve pro thesis; and do not have any internal electrical devices, such as a cackler implant or spinal cord stimulator.

There will be no costs to me as a result of my participation in this study, and I will receive $50.00 (fifty dollars) as monetary compensation for the additional time this exam takes beyond my regular ARIC visit.

I understand that the use of the MRI scan will not replace any other diagnostic procedure which might be of benefit to my health. I am aware that I may refuse to have an MRI, and may withdraw from this study at any time. Neither failure to join or withdrawal from this study will affect the availability of my medical care at Bowman Gray School of Medicine.

The ARIC study does not provide diagnosis, medical advice or treatment to participants. During the course of this study, if an abnormality is found on the MRI scan which requires medical follow-up, my personal physician and I will be informed.

If an injury or illness occurs as a direct result of my participation in this study, Bowman Gray School of Medicine will pay for medical treatment reasonably necessary to treat that injury or illness. No other compensation is available.

This study has been approved by the Institutional Review Board of this institution.

Further information about the study or my participation in it is available from the investigator(s), Dr. Fred Romm or Jeannette Bensen at (919) 777-3040.

I understand that my medical records will be confidential, but that they may be reviewed by representatives of the National Heart, Lung and Blood Institute which has funded this study. I understand that my identity will be kept confidential in any publication or public disclosure of the information resulting from this study.

I have been given the opportunity to ask questions about this procedure and have received answers that I understand. This study has been explained to me to my satisfaction and I agree to participate.

_____

Participant's signature Date

_____

Participant's name

_____

Person informing participant Date

_____

Witness Date

Appendix 1.4 MRI Procedure Form

ARIC MRI PROCEDURE FORM

Atherosclerosis Risk in Communities

ID NUMBER: | | | | | | | | CONTACT YEAR: | | | FORM CODE: M P R VERSION: A 04-06-93

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

Public reporting burden for this collection of information is estimated to average 2 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing this burden to Reports Clearance Officer, PHS, 721-H Hubert H. Humphrey Bldg., 200 Independence Ave. SW, Washington, D.C. 20201, Attn. PRA; and to the Office of Management and Budget, Paperwork Reduction Project (OMB 0925-0281), Washington, D.C. 20503.

INSTRUCTIONS: This form should be completed on paper during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

MRI PROCEDURE FORM (MPRA screen 1 of 2)

1. Status of MRI procedure:

Go to Item 3b.	Completed	C
Go to Item 3a.	Attempted, incomplete	I
	Not attempted	N

2. The reason MRI was not attempted:

No show	A
Rescheduled	B
Refused to sign informed consent form	C
Refused for other reasons (specify)	D
Other (specify)	E

Specify: _____

GO TO ITEM 7, SCREEN 2.

3.a. Reason for incomplete MRI:

Claustrophobia	C
Other (Specify)	O

Specify: _____

b. Date MRI attempted or completed:

		/			/		
M	M		D	D		Y	Y

4. Record the order of Scanning Pulse Sequence. (If all series were completed in order, enter 1, 2, 3)

OPTIONS:

Series 1: T1 Sagittal	1
Series 2: Spin density/ T2 Oblique Axial	2
Series 3: Oblique Axial	3
Other	4

IF 4 IS ENTERED, PLEASE EXPLAIN BELOW:

_____

MRI PROCEDURE FORM (MPRA screen 2 of 2)

5. Was oblique axial scan parallel to the AC/PC line? ..... Yes Y

No N

6.a. Were any emergent alert conditions noted? ..... Yes Y

No N

Go to Item 7.

b. Specify the alert condition:

6.c. Who was notified of this alert?

d. Date of alert notification:

M M D D Y Y

7. MRI Technologist initials:

8. Date of data collection:

M M D D Y Y

TO BE COMPLETED BY MRI READING CENTER:

Tape Number:

Date Received:

M M D D Y Y

Date Archived:

M M D D Y Y

Date of dBase Entry:

M M D D Y Y

Appendix 1.5 QxQ Instructions for the MRI Procedure Form

INSTRUCTIONS FOR THE MRI PROCEDURE FORM
MPR, VERSION A: 04-06-93
PREPARED 10-14-93

The MRI Procedure Form (MPR) is completed by the MRI technologist during the course of the MRI scan. The primary purposes of the form are to record whether the scan was completed, document the reasons for not attempting or completing the scan, record the scanning pulse sequence, verify that the oblique axial scan was taken parallel to the AC/PC line, document the presence of any emergent alert conditions, who was notified of this condition and the date of notification.

The questionnaire is completed by the MRI technologist at the MRI center at different stages during the procedure. A form is completed for every participant who is scheduled for an MRI by the field center, regardless of whether the MRI Center Informed Consent document is signed or the scan is initiated and prematurely terminated.

The MRI Procedure Form is collected using the paper version of the form. No questions are read to the participant. If a response needs to be changed after it has been entered, an 'X' is placed over the incorrect numeric or multiple choice response. For numeric entries, the correct response is clearly written above the incorrect entry. For 'multiple choice' and 'yes/no' responses, the correct response is circled. If there is additional information (for which there is no data entry field) that could be of use to staff at the field center or the MRI reading center, write it on the form. This information, however, will not become part of the database.

1. The completion status of the MRI scan is entered once the technologist is certain of its status. This can be done either at the beginning of the procedure and corrected as required at the end of the study or completed at the end of the procedure, at the discretion of the technologist.

   If the scan is not attempted, enter 'N' and the reason for not doing the scan in Item 2.

   If the scan is started and prematurely terminated, enter 'I'. The reason for not completing the scan is entered in Item 3.a and the date on which it was performed is entered in Item 3.b.

   If the scan is started and completed, enter 'C' and the scan date in Item 3.b, leaving the intervening items blank.

2. Item 2 is completed when the scan is not attempted. Several common reasons for not attempting the scan are available as response categories. Select only one. If more than one response category applies, or if there is another reason, select OTHER, and enter the reason in the space provided. Complete the administrative data (Items 7 and 8) at the end of the form. Send the form to the ARIC field center.

3.a Enter the reason the scan was not completed, selecting claustrophobia (C) or other (O). If there are multiple reasons, including claustrophobia, select 'C' in preference to the other reasons. If the scan was not completed for a reason other than claustrophobia, select 'O' and enter the reason in the space provided (SPECIFY).

3.b Enter the date on which the scan is performed regardless of whether the scan is terminated prior to completion or the scan is completed, using the standard date format.

When the scan is terminated prior to the collection of any data, leave Items 4-6 blank and go to Item 7. When the scan includes some data, continue with Item 4.

4. Record in the three boxes the sequence in which the scanning pulses are performed. If all series were completed in order, enter 1, 2, 3. If one or more of the series is not completed or one or more of the standard series are repeated, enter 4 in the appropriate box and record the final pulse sequence on the line below.

5. Indicate whether the oblique axial scan was done parallel to the AC/PC line.

6. Record the presence or absence of any emergent alert conditions, as defined in the MRI protocol. If none are present (NO), go to Item 7. If YES, specify the alert condition in Item 6.b, record the name of the neuroradiologist who reviews the possible alert condition, and record the date on which the field center is notified of the alert condition.

If the MRI radiologist does not feel the condition observed on the scan warrants alert status, correct 6.a, 6.b and 6.c.

7. Enter the MRI technologist's initials.

8. Enter the date on which the form is completed.

Appendix 1.6 MRI Magnetic Tape Weekly Log Sheet

ARIC MRI Magnetic Tape Weekly Log Sheet

DATES: __ / __ / __ TO: __ / __ / __ PAGE __ OF __
mo day year mo day year

FIELD CENTER: _____

FORM COMPLETED BY: _____

Field Center please complete	
Place Participant Label below	Date MRI completed

MRI Reading Center use only

Appendix 1.7 MRI Completion Form

ARIC MRI COMPLETION FORM

NAME: _____

ID#: _____

TO BE COMPLETED BY MRI TECHNOLOGIST

_____ _____ _____

Please fill in the blanks with the order of Scanning Pulse Sequence
(if all series were completed in order, enter 1 2 3)

Options:
1 = Series 1: T1 Sagittal
2 = Series 2: Spin density/T2 Oblique Axial
3 = Series 3: Oblique Axial
4 = Other, explain:

Was oblique axial scan parallel to the AC/PC line? ☐ YES ☐ NO

Were there any emergent alert conditions noted? ☐ YES ☐ NO

↓

Specify the condition:

Who was notified?

Date: __ __ / __ __ / __ __

Technician: Date:

TO BE COMPLETED BY MRI READING CENTER

Tape number:
Date received: __ __ / __ __ / __ __
Date archived: __ __ / __ __ / __ __
Date of dBase entry: __ __ / __ __ / __ __

Appendix 1.8 ARIC Optical Disk Log

OPTICAL DISK LOG

LOG FOR DISK #_____

PARTICIPATION ID# AND INITIALS	DATE OF MR STUDY	DATE OF SHIPMENT	*COMPLETED BY MR RC* DATE OF ARCHIVE

ARIC STUDY COORDINATOR TO COPY THIS LOG AND RETAIN AT FC AND SEND ORIGINAL TO MR RC

APPENDIX 2.0 COVER LETTERS REPORTING RESULTS FOR MRI

Appendix 2.1 Physician: Normal Results

<DATE>

<NAME> <ADDRESS>

Dear Dr. <NAME>:

<NAME>, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. The scanning protocol was an abbreviated research MRI and is not equivalent to a standard clinical study. Your patient requested that we send you the results of this MRI scan. The results of this cerebral MRI performed on <DATE> are reported below.

Normal for age

We have mailed a letter to <NAME> to report that no abnormalities were found in this scan, and that this was reported to you. Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

_____, M.D.
Medical Director

Enclosures

Appendix 2.2 Physician: Minor Abnormal Findings, No Referral

<DATE>

<NAME> <ADDRESS>

Dear Dr. <NAME>:

<NAME>, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. The scanning protocol was an abbreviated research MRI and is not equivalent to a standard clinical study. The ARIC Study does not provide diagnosis, medical advice or treatment. Your patient requested that we send you the results of this MRI scan.

The results of this cerebral MRI performed on <DATE> are reported below.

TYPE	PRESENT	NUMBER	SIDE	LOCATION
Old Infarct > 5 mm				
Old Hematoma				

The clinical significance of these findings is not known, because this type of study is not usually performed in asymptomatic subjects.

We have mailed a letter to <NAME> to report that there were minor chronic findings which are often seen on MRI, which should not be a cause for concern and that this was reported to you. Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

_____, M.D.
Medical Director

Enclosures

Appendix 2.3 Physician: Abnormal Results

<DATE>

<NAME> <ADDRESS>

Dear Dr. <NAME>:

<NAME>, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. The scanning protocol was an abbreviated research MRI and not equivalent to a standard clinical study. Your patient requested that we send you the results of this MRI scan.

The results of this cerebral MRI performed on <DATE> are reported below.

<FINDING>

A report from Dr. <NAME> is attached for your information. These findings should be considered in the context of the patient's medical history.

The ARIC Study does not provide diagnoses, medical advice, nor treatment. We have recommended to <NAME> that <HE/SHE> contact you within <TIME FRAME> to determine how to follow up on these results.

Should you have any questions, please feel free to contact us at <PHONE>.

Sincerely,

_____, M.D.
Medical Director

Appendix 2.4 Physician: Abnormal Results, Participant Not Informed

<DATE>

<NAME> <ADDRESS>

Dear Dr. <NAME>:

<NAME>, a patient of yours, participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors, as part of the Atherosclerosis Risk in Communities (ARIC) Study. The scanning protocol was an abbreviated research MRI and not equivalent to a standard clinical study. Your patient requested that we send you the results of this MRI scan.

The results of this cerebral MRI performed on <DATE> are reported below.

<FINDING>

A report from Dr. <NAME> is attached for your information. These findings should be considered in the context of the patient's medical history.

The ARIC Study does not provide diagnoses, medical advice, nor treatment. **Due to the longstanding nature of this MRI finding your patient has not been notified**.

Should you have any questions, please feel free to contact us at <PHONE>.

Sincerely,

_____, M.D.
Medical Director

Appendix 2.5 Participant: Normal Results

<DATE>

<NAME> <ADDRESS>

Dear <NAME>:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. The results of your MRI scan of the brain are reported below.

Your scan is in the normal range

We have communicated these results to your physician, Dr. <NAME>. Please remember that this MRI examination is for research purposes and is not the same as the standard MRI exam which you doctor might order. If you have any questions in this regard, please feel free to contact us at <PHONE>.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

Appendix 2.6 Participant: Minor Abnormal Findings, No Referral

<DATE>

<NAME> <ADDRESS>

Dear <NAME>:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. The results of your MRI scan of the brain are reported below.

> There are minor chronic findings which are often seen on MRI. These should not be a cause for concern on your part.

We have communicated these results to your physician, DR. <NAME>. Please remember that this MRI examination is for research purposes and is <u>not</u> the same as the standard MRI exam which you doctor might order. If you have any questions in this regard, please feel free to contact us at <PHONE>.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

Appendix 2.7 Participant: Abnormal Results, Referral Recommended

<DATE>

<NAME> <ADDRESS>

Dear <NAME>:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. The results of your MRI scan of the brain are reported below.

> There is a finding which may require further medical evaluation. We have communicated these results to your physician, DR. <NAME>. Please contact your physician to determine how to follow up on these results.

Please remember that this MRI examination is for research purposes and is <u>not</u> the same as the standard MRI exam which you doctor might order. If you have any questions in this regard, please feel free to contact us at <PHONE>.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

Appendix 2.8 Participant: Normal or Abnormal Results, No MD Designated

<DATE>

<NAME> <ADDRESS>

Dear <NAME>:

Thank you for taking part in the study of magnetic resonance imaging (MRI) of the brain as part of the ARIC Study. We are grateful for your time and effort. During your ARIC visit you indicated that we should send the results of this exam to you.

Your scan is in the normal range

-- OR --

There are minor chronic findings which are often seen on MRI. These should not be a cause for concern on your part.

-- OR --

There is a finding which may require further medical evaluation. A copy of the report from a specialist is enclosed. Please contact your physician to determine how to follow up on these results. If you do not have a personal physician or do not know where to find one we suggest that you call <LOCAL MEDICAL SOCIETY, TELEPHONE #>.

If you find that the attached report is not clear, please call us at <TELEPHONE #>.

Thank you again for your participation in the ARIC Study.

Sincerely,

_____, M.D.
Medical Director

Enclosure